

### **AMENDMENTS TO THE CLAIMS**

This listing of claims will replace all prior versions, and listings, of claims in the application.

#### **Listing of Claims:**

1-44. **(Cancelled).**

45. **(Currently Amended)** A method for analyzing immune system cycling to determine when an agent should be administered to a patient suffering from a disease characterized by the production of regulator cells, the method comprising

i) monitoring the patient, or samples obtained therefrom, for at least one of:

- a) effector cell numbers and/or activity,
- b) regulator cell numbers and/or activity,
- c) a molecule associated with the disease, and/or
- d) an immune system marker,

wherein the monitoring is conducted for a period of time that represents at least one cycle of the immune system,

ii) analysing the results from step i) to understand the dynamics of the persistent immune system cycling within the patient, and

iii) based on the cycling of the immune system, determining when the agent is to be administered, wherein the agent is to be administered when regulator cell numbers and/or activity are increasing in the cycle, and wherein the agent inhibits the production of, limits the function of, and/or destroys, regulator cells.

46. **(Currently Amended)** A method of treating a disease characterized by the production of regulator cells, the method comprising;

i) analyzing immune system cycling by monitoring a patient suffering from the disease, or samples obtained therefrom, for at least one of:

- a) number and/or activity of regulator cells,
- b) number and/or activity of effector cells,
- c) a molecule associated with the disease, and/or
- d) an immune system marker,

wherein the monitoring is conducted for a period of time that represents at least one cycle of the immune system,

ii) analysing the results from step i) to understand the dynamics of the persistent immune system cycling within the patient, and

iii) exposing the patient to an agent to treat the disease, wherein the agent is administered when regulator cell numbers and/or activity are increasing in the cycle, and wherein the agent inhibits the production of, limits the function of, and/or destroys, regulator cells.

47. **(Previously Presented)** The method of claim 45, wherein the disease characterized by the production of regulator cells is cancer or an infection.

48. **(Withdrawn)** The method of claim 45, wherein the patient is infected with HIV, Hepatitis B virus or Hepatitis C virus.

49. **(Previously Presented)** The method of claim 45, wherein the immune system marker reflects the number and/or activity of regulator cells, and/or the number and/or activity of effector cells.

50. **(Previously Presented)** The method of claim 45, wherein the immune system marker is an acute phase inflammatory marker.

51. **(Cancelled)**

52. **(Withdrawn)** The method of claim 46, wherein the agent is administered about when CD4+CD8- T cells are detected.

53. **(Withdrawn)** The method of claim 46, wherein the agent is administered approximately when CD8+CD4- T cell numbers have peaked.

54. **(Withdrawn)** The method of claim 46, wherein the molecule associated with the disease is an antigen produced by a cancer cell or an infectious agent.

55. **(Withdrawn)** The method of claim 46, wherein the agent is administered approximately when levels of the molecule associated with the disease begin to decrease.

56. **(Withdrawn)** The method of claim 46, wherein the patient is monitored for an acute phase inflammatory marker, and a molecule associated with the disease.

57. **(Cancelled)**

58. **(Previously Presented)** The method of claim 45, wherein the patient is monitored for a period of at least 21 days.

59. **(Previously Presented)** The method of claim 45, the patient is monitored at least about every 3 days.

60. **(Cancelled)**

61. **(Previously Presented)** The method of claim 45, wherein the patient has not been exposed to a treatment for the disease for at least 21 days.

62. **(Previously Presented)** The method of claim 45, wherein the patient is a human.

63. **(Withdrawn - Currently Amended)** A method for analysing immune system cycling to diagnose a disease characterized by the production of regulator cells, the method comprising

i) monitoring the patient, or samples obtained therefrom, for at least one of:

- a) effector cell numbers and/or activity,
- b) regulator cell numbers and/or activity,
- c) a molecule associated with the disease, and/or
- d) an immune system marker, and

wherein the monitoring is conducted for a period of time that represents at least one cycle of the immune system,

ii) analysing the results from step i) to understand the dynamics of the persistent immune system cycling within the patient,

wherein cycling of any one of a) to d) indicates the disease is present.

64. **(Withdrawn-Currently Amended)** A method for analysing immune system cycling to determine when a vaccine should be administered to a patient suffering from a disease characterized by the production of regulator cells, the method comprising

- i) monitoring the patient, or samples obtained therefrom, for at least one of:
  - a) effector cell numbers and/or activity,
  - b) regulator cell numbers and/or activity,
  - c) a molecule associated with the disease, and/or
  - d) an immune system marker,wherein the monitoring is conducted for a period of time that represents at least one cycle of the immune system,
- ii) analysing the results from step i) to understand the dynamics of the persistent immune system cycling within the patient, and
- iii) based on the cycling of the immune system determining when the agent is to be administered, wherein the agent is to be administered when regulator cell numbers and/or activity are increasing in the cycle, and wherein the agent inhibits the production of, limits the function of, and/or destroys, regulator cells.

65. **(Withdrawn-Currently Amended)** A method of treating a disease characterized by the production of regulator cells, the method comprising;

- i) analysing immune system cycling by monitoring a patient suffering from the disease, or samples obtained therefrom, for at least one of:
  - a) number and/or activity of regulator cells,
  - b) number and/or activity of effector cells,
  - c) a molecule associated with the disease, and/or
  - d) an immune system marker, ~~and~~wherein the monitoring is conducted for a period of time that represents at least one cycle of the immune system,
- ii) analysing the results from step i) to understand the dynamics of the persistent immune system cycling within the patient, and
- iii) exposing the patient to a vaccine to treat the disease, wherein the agent is administered when regulator cell numbers and/or activity are increasing in the cycle, and wherein the agent inhibits the production of, limits the function of, and/or destroys, regulator cells.

66-75. **(Cancelled)**